



02-MAR-1998-0515



McNEIL CONSUMER I
FORT WASHINGTON

Page _____



3040673-1-00

FDA use only

A. Patient information				C. Suspect medication(s)			
1. Patient identifier [redacted] In confidence	2. Age at time of event: or 21 yrs Date of birth: [redacted]	3. Sex () female (X) male	4. Weight 170 lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 TYLENOL Analgesic Unknown #2			
B. Adverse event or product problem				2. Dose, frequency & route used #1 unknown dose, po #2			
1. X Adverse event and/or Product problem (s.g., defects/malfunctions)				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 1996-4/27/97 #2		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A	
2. Outcomes attributed to adverse event (check all that apply) (X) death (4/27/97) () disability () life-threatening () congenital anomaly () hospitalization - initial or prolonged () required intervention to prevent permanent impairment/damage () other:				4. Diagnosis for use (indication) #1 minimize pain associated with injuries #2		7. Exp. date (if known) #1 Unknown #2	
3. Date of event (mo/day/yr) 4/27/97		4. Date of this report (mo/day/yr) 02/19/98		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A			
5. Describe event or problem Notification via attorney letter & medical records of DEATH in a 21 yo male allegedly associated w/the use of a TYLENOL® acetaminophen product. Report indicates a 21YO M on or about 10/20/95 fell into stairwell & sustained extensive injuries; TYLOX® prescribed for pain management. After TYLOX® expired, he began taking Tylenol to help minimize the pain associated w/his injuries. Reportedly, pain persisted & he continued taking Tylenol throughout the 1996-1997 winter season. On evening(4/26/97) at friend's home, he consumed some beer & went to companion's home. After 3-4 hrs he became extremely ill & went to BR. After a reasonable period of time, friend went to check on him & found him dead in BR. Ambulance arrived & found pt in resp-cardiac arrest (HEART ARREST), airway obstructed (ASPHYXIA) w/vomitus. CPR & supportive measures used enroute to ER. In ER, resuscitation w/ACLS protocol was unsuccessful, pt expired(4/27/97). Dx death (alcohol/drug related). Police report lists cause of death: Pulmonary edema (LUNG EDEMA) due to HEPATIC FAILURE & polypharmacy.				9. NDC # - for product problems only (if known) - -			
6. Relevant tests/laboratory data, including dates 4/27/97 PT=13.7 secs, INR=1.27, PTT=52.3 secs, glucose=309 mg/dL, Creat=1.6 mg/dL, Na=154 mmol/L, K=5.9 mmol/L, AST=813 U/L, LDH=1353 U/L, CK=1199 U/L, ALT=1041 U/L, P=18.9 mg/dL, Mg=3.2 mg/dL, serum alcohol=218.5 mg/dL(See Sect. 7)				10. Concomitant medical products and therapy dates (exclude treatment of event) pt had possible access to the following drugs from police evidence report: empty containers of Alaprazolam, ENDOCET®, Propoxyphene Napsy w/apap & containers w/Amitriptyline HCl, PERCOFET®, ZANTAC® & ELAVIL®			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) hx of prior injuries from a fall; NKDA; Corr Act. B. 6. pH=6.79, PCO2=31.2, HCO3=4.8, PO2=100.1, SaO2=89.4% on 100% Ambu, WBC=14.1; Postmortem Profile: (urine) ethanol=0.256 & 0.137%, propoxy & metabolite= positive; (blood) ethanol= 211 & 0.137 g/dL(X), salicylates= 8 & 6 mcg/ml, acetaminophen= 102 & 106 mcg/ml; (gastric) alcohol=0.246				G. All manufacturers			
				1. Contact office - name/address (& mfring site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-233-7820	
				4. Date received by manufacturer (mo/day/yr) 01/16/98		3. Report source (check all that apply) () foreign () study () literature () consumer () health professional () user facility () company representative () distributor (X) other: attorney	
				5. (A) NDA # 17-552 IND # PLA # pre-1938 () Yes OTC product (X) Yes			
				6. If IND, protocol #			
				7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #		8. Adverse event term(s) DEATH OVERDOSE HEART ARREST ASPHYXIA EDEMA LUNG LIVER FAILURE	
				9. Mfr. report number 0936266A			
				E. Initial reporter			
				1. Name, address & phone # [redacted] Esq. [redacted] associates [redacted] street			
2. Health professional? () Yes (X) No		3. Occupation attorney		4. Initial reporter also sent report to FDA () Yes () No (X) Unk			